

Department of Health and Human Service
Prescription Drug Importation Task Force

March 19, 2004 – FDA Offices, Rockville, Maryland

Presentation before Task Force

Peter T. Wyckoff

Minnesota Senior Federation-Metropolitan Region, Executive Director

National Coalition of Consumer Organizations on Aging (NCCO), Prescription Drug Convener of Prescription
Drug Importation Task Force

- I. Introduction (Slides 1-6)
 - A. Personal
 - B. Minnesota Senior Federation
 - B. National Coalition of Consumer Organizations on Aging

- II. Background on our Experience with Canadian Bus Trip Importation Issues (Slides 27-29)
 - A. Drug Runs to Winnipeg, Manitoba starting in 1995
 - B. Trips currently paid for by the salary of our U.S. Senator Mark Dayton
 - C. Lessons Learned
 - 1. Average savings of 49%
 - 2. Apothecaries are alive and well in Canada as opposed to a crisis in pharmaceutical access in this country at least in part caused by the actions of the FDA to not allow American pharmacies to import drugs from FDA approved facilities in other industrialized countries.
 - 3. Canadians are very nice.

- III. Background on U.S. Consumer Organizations negotiations with Canadian Pharmacies
 - A. Began in Fall of 2001 through NCCO- Strong state based non-profit senior organizations in Massachusetts, New York, Indiana, Pennsylvania, Wisconsin, and Minnesota
 - 1. Included surveys, Review of process and services
 - 2. Site Visits
 - 3. Willingness to negotiate with our organizations
 - 4. Pilot Programs
 - 5. Launched of programs late fall of 2002 and January of 2003

 - B. U.S. Consumer Negotiated Programs are currently operated by Coalition of Wisconsin Aging Groups out of Madison, United Seniors Action of Indiana out of Indianapolis, and the Minnesota Senior Federation from St. Paul.

(www.mnseniors.org)
(Slides 31-38)

 - 1. On a basket of 13 drugs surveyed as we started the program in January of 2003 our negotiated prices were 62% less expensive than Twin Cities average prices and 15% to 45% less expensive than the other Canadian exporting Pharmacies.
 - 2. In an AARP Bulletin survey on April of 2003 of six medications, Canadian exporting pharmacy prices were 46% below on an aggregate of four Canadian Pharmacies surveyed and the Minnesota Senior Federation program was an additional 15% lower than the other Canadian Pharmacies. As a result our organization, situated on the east side of Lake Wobegon, now has thousands of members from all 50 states.
 - 3. We are not in this for a program but rather to further the issue of affordable and lower prescription drug prices for all Americans
 - 4. Not one quality or professional problem in our 18 months of operation with thousands of prescriptions being filled monthly.
Not one contaminated, not one counterfeit, not one professional mistake in filling the US doctor's prescription.

MINNESOTA SENIOR FEDERATION



US Department of Health & Human Service Drug Importation Task Force

March 19, 2004

Minnesota Senior Federation



Minnesota Senior Federation

Who we are:

- Largest grassroots advocacy organization of seniors in Minnesota
- 31 Year Old, Non-profit, non-partisan
- Represent 110 affiliated organizations & 150,000 older Minnesotans
- 25,000 individual members across the state.
- Serve 60,000 persons annually

Our mission is to empower seniors across the state of Minnesota to meet their own and community needs and concerns.

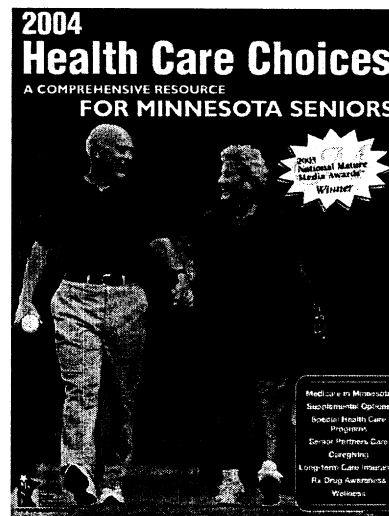


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- To provide consumer education for the entire community and benefits that enhance the value of membership.



Our Vision:



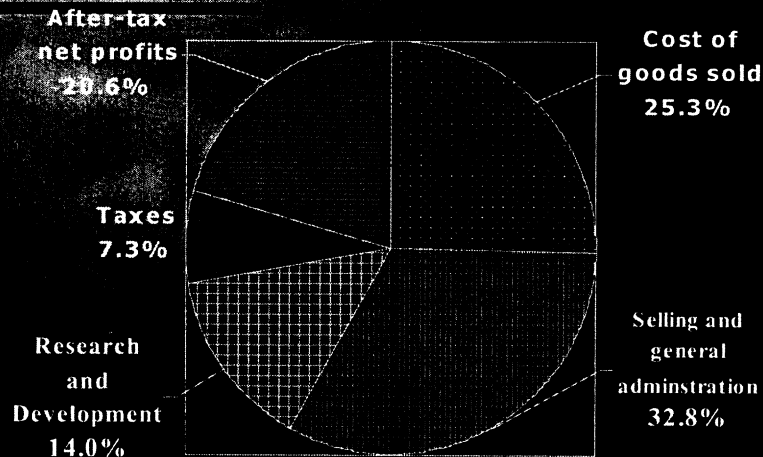
National Coalition of Consumer Organizations On Aging (NCCO)

- State and Locally Based Senior Consumer Organizations in Fifteen States
 - All non-profit and non-partisan
 - All controlled by their members
- Senior Action Alliance (Philadelphia)
- Massachusetts Senior Action
- New York State Wide Senior Action Council
- Coalition of Wisconsin Aging Groups (CWAG)
- United Senior Action – Indiana
- Minnesota Senior Federation
- Senior Action Network (SAN – San Francisco)

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Allocation of Revenue Dollars in Thirteen Large Research-Based Pharmaceutical Companies 2002*

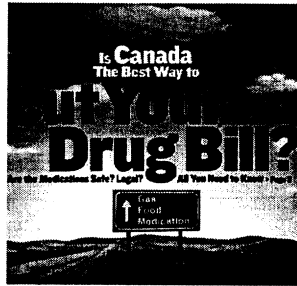


*Chart from Uwe Reinhardt's "An Evaluation of Performance for the Pharmaceutical Market" in *Health Affairs*, Volume 23, Number 1, 1995

Consumer Perspective on Safety, Effectiveness & Cost

“A drug that one cannot afford is neither safe nor effective.”

-- Stephen W. Schondelmeyer
PRIME Institute, 1996



Key Issues

•Savings

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Importation Savings

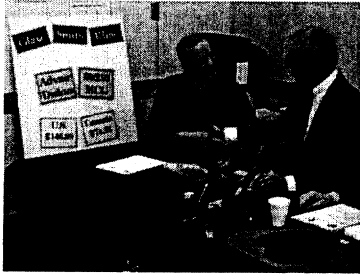
- Average of 45% savings
- MN Senior Federation Drug runs to Winnipeg showed average savings of 49%
- Not all drugs available
- Not all drugs less expensive



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GlaxoSmithKline Products

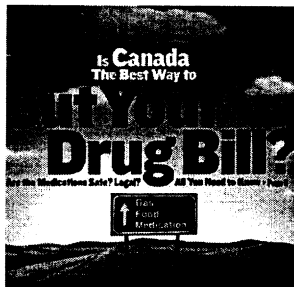


- Advair, Agenerase, Augmentin, Avandia, Bactroban, Combivir, Coreg, Epivir-HBV, Flonase, Flovent, Hycamtin, Imitrex, Malarone, Paxil, Requip, Serevent, Timentin, Valtrex, Ventolin, Wellbutrin SR, Ziagen, Zofran, and Zyban.

- Average savings of **52%**

Minnesota Senior Federation

March, 2003



Key Issues

• Safety

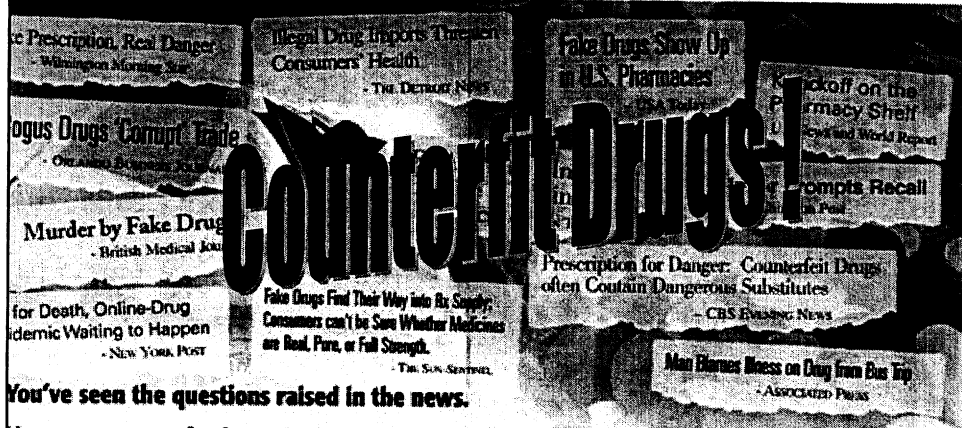


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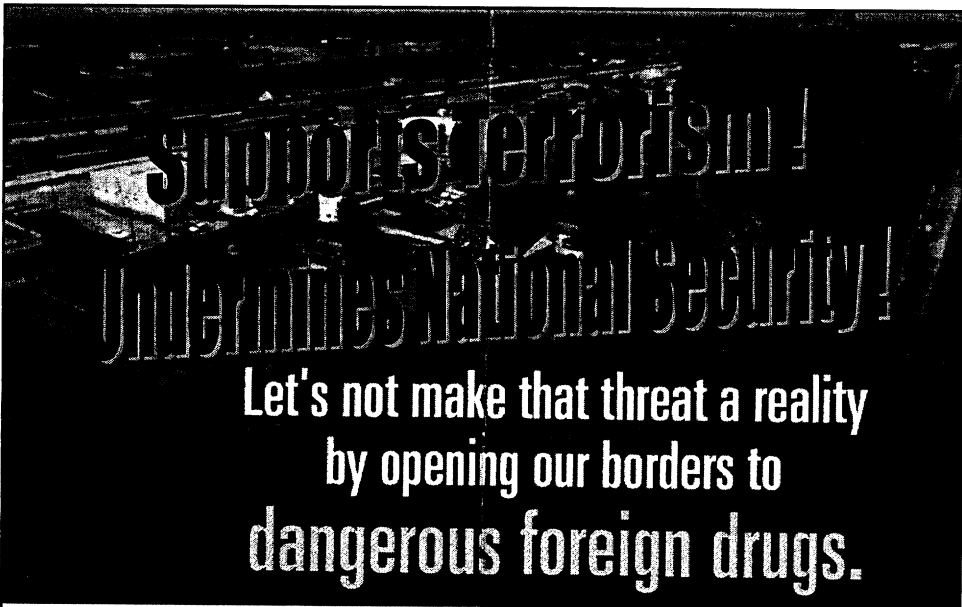
PUBLIC HEALTH ALERT:
Investigative Reports Expose Danger
of Imported Medicines for Seniors

PRESTIGE FIRST CLASS
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PAID
ADVANCED MAILING
SERVICES



You've seen the questions raised in the news.

Now, see reverse for important warnings from
U.S. and Canadian Health Officials for seniors
and Congressman Jim Ramstad about the
dangers of imported and counterfeit medicines.



Importing from Canada - Yes

Yes

'Best Way to Get Affordable Drugs'

By PETER WYCKOFF

Barry released at the launch of the Minnesota Senior Federation's pantheorizing Canadian importation program revealed a dramatic 42 percent savings on a basket of commonly prescribed prescription medications and a 5.5 percent overall savings on prescriptions for GlaxoSmithKline drugs.

While the argument against importation is primarily one of safety, we should heed the wisdom of Stephen Schindler, mayor of the U.S.



is cheaper in Canada, if they make decisions."

AARP Bulletin - May 2003
Used with permission

variety of Minnesota School of Pharmacy: "A drug that is not affordable or not effective."

The U.S. Food and Drug Administration (FDA) obviously cannot guarantee the safety of medications purchased in Canada. Further, consumers rely on the oversight of the Canadian Ministry of Health, which maintains its responsibility as well as the FDA. While we are not aware of contaminated drugs coming from any Canadian regulated pharmacy, we are all too aware of examples of counterfeit, contaminated and impure drugs in the United States such as adulterated chemotherapy drugs from a Kansas City pharmacy's drugs manufactured for the Canadian market come from the same FDA-approved facilities as those destined for the American market.

Buying prescription drugs from any mail order source is not the ideal way to purchase medications. But for hundreds of thousands of Americans, buying from licensed Canadian pharmacies is the best way to get affordable, safe and effective medications. Permitting prescription importation would increase a viable option for the health, life and safety of thousands of uninsured Americans.

The real debate now before Congress is whether by joining the rest of the world in negotiating prescription drug prices, we will put the needs of our citizens ahead of the excessive profits of the pharmaceutical industry. "Just that time," one Republican congressman said the Senate Federation, "we need to be able to rely on the power of international free trade to help bring down the cost of prescription drugs."

- **No incidents of contaminated, impure, or counterfeit drugs from licensed Canadian Pharmacies**
- ***Canadian authorities regulate the quality of medications manufactured and sold there as rigorously as the FDA does in the United States.***

— Congressional Research Service -2001

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Importing from Canada - Yes



"All imported drugs must be equally safe and effective whether they are for use by Canadians or for export."

—Canadian health ministry, May 2003

"We appreciate that [Canadian officials] are stepping up to this difficult challenge where we don't have the regulatory authority, and they might. The fact that they are explicitly stating that they are trying to assure safety and effectiveness not only for Canadians, but for the millions of prescriptions sold to Americans through Canada, is a potentially useful step."

— FDA Commissioner Mark McClellan

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Importing Prescriptions from Canada

• Bus Trips to Canada

- Inaugurated by Minnesota Senior Federation in 1995
- Now supported by the salary of U.S. Senator Mark Dayton
- Average savings of 49%



2003–2004 MnSF CanadaRx Express

U.S. seniors save money in Canada, lose patience

Many angered by
impasse on drugs

By Tim Jones
Tribune national correspondent

WINNIPEG, Manitoba — Melvyn and Fern Pylka spent the sunshine hours of their wedding anniversary last week on a charter bus, hoping to toast their 48 years together with a nice, big price break on Fosamax, a popular drug to treat osteoporosis.

- Allows direct contact with pharmacist and doctor
- Dramatizes need for lower cost prescription drugs
- Trips resume March 2004



Minnesota seniors arrive at a Winnipeg doctor's clinic for exams and prescriptions after a 30-hour, 25-mile bus journey that meandered from Duluth to Winnipeg last week.

Chicago Tribune

MnSF Canadian Importation Program Resulted from



- Year long investigation by NCCO senior consumer organizations
- Three month negotiation and seven month Pilot Program in 2002
- MnSF-CanadaRx Program began in January 2003
- MnSF-Extended Care Pharmacy added in January 2004

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MnSF Canadian Importation Program

- Benefit of Federation Membership
- First US Consumer Negotiated Programs with Canadian Pharmacies



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MnSF Canadian Importation Canada RX Program

Federation Survey on common prescription drugs:

- **62% Average savings**
over Twin Cities
Pharmacies
- MnSF Program is **15%**
to 41% less expensive
than other Canadian
Exporters



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NEWS&TRENDS

NORTH FOR DRUGS
CONTINUED FROM PAGE 3
she says. "That was not a
to do." Buying by mail from
da, even with shipping cost
outlay by 42 percent.

Sandra Barron, of Silver
Md., used to spend a third
monthly Social Security
medications at the cheapest
pharmacy she could find.
year, she says, "I discovered
da. My drug costs went from
\$430 to \$160 a month.
enormous difference." She
more than \$3,240 a year
than 60 percent.

Canadian mail-order phar-
do not supply all medications
ally they focus on long-term
nance drugs—most often
made—that older people can
use. Even among these phar-
prices vary a good deal,
there is no website that al-
sumers to compare them.

This is one reason why
Minnesota Senior Federation
formed its Prescription Dis-
tribution Center, a program
Americans of all ages get
possible deal along with qu-
rections. During a seven-
lot project, it vetted, tested
gotiated with a licensed
pharmacy that agreed to c-
fees to provide a dis-
er discounts. This resulted
first consumer-negotiated
come out of Canada," Wyckoff says.

HOW DO INTERNET MAIL-ORDER PRICES COMPARE?

All prices in U.S. dollars, as of March 12, 2003, and subject to change

	STRENGTH/ QUANTITY	UNITED STATES MAIL ORDER	CANADIAN MAIL ORDER	MINNESOTA SENIOR FEDERATION
 Celebrex Arthritis	100mg/100	\$150.27	\$72.27	\$56.98
 Glucophage Diabetes	500mg/100	\$61.87*	\$23.49†	\$15.16†
 Lipitor Cholesterol	20mg/90	\$286.74	\$164.78	\$153.35
 Norvasc Hypertension	10mg/100	\$184.78	\$161.16	\$153.28
 Paxil Depression	10mg/30	\$74.21	\$51.26	\$43.48
 Tamoxifen Breast Cancer	20mg/100	\$232.96*	\$61.38†	\$32.90†

SOURCES: AARP BULLETIN AVERAGE OF MAIL ORDER PRICES FROM FOUR U.S. AND FOUR CANADIAN PHARMACY WEBSITES, AND PRICES POSTED ON THE NSF WEBSITE, MARCH 12, 2003.

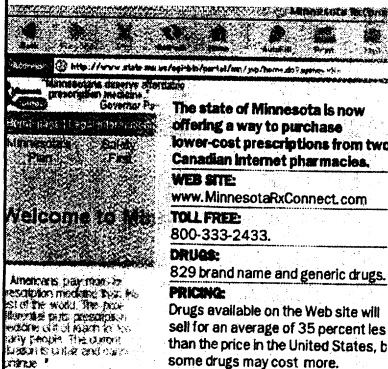
*U.S. Generic
†Canadian Generic

offer to sell prescription drugs at that say prescriptions are not

to submit de-
cal history

[go to other countries] in search of
medications they need at prices
they can afford."
Meanwhile many consumers say

MN State's Canadian Importation Program

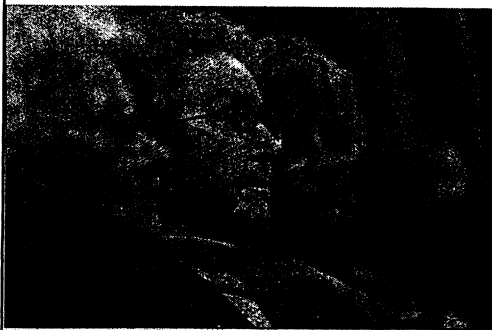


- ☐ State Sent Inspectors to Canada
- ☐ Approved two pharmacies
 - ☐ Total Care Pharmacy in Calgary
 - ☐ Granville Pharmacy in Vancouver
- ☐ Program does not negotiate prices
- ☐ Phone: 800-333-2433
- ☐ www.MnRxConnect.com

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MN State Program Patterned after Federation's Canadian Importation Program



Members of the Minnesota Senior Federation, which already had a Web site link to Canadian pharmacies, attended Gov. Tim Pawlenty's news conference Friday introducing the state's new Web site.

- ✓ Federation negotiated lower prices for members
- ✓ Lower Mailing Costs
- ✓ Additional Consumer Protections

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Pharmaceutical Industry's Attacks

- Glaxco-Smith Kline, Pfizer, Astra Zeneca, Lilly,
- Actions punish seniors in need of affordable prescriptions drugs.
- Trying to create their own foreign policy by limiting international free trade.
- Companies willing to imperil the health of Americans to continue and increase their exorbitant net profits.
- For hundreds of thousands of Americans, the ability to get lower cost prescription drugs through Canada is actually a matter of health or illness, life or death.

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Two Sources to Lower the cost of prescription drugs

- **MNSF Prescription Drug Price Information Center**

- Minnesota Senior Federation
- All Options including Importation

1-645- 0261

1-877-645-0261

Ext 124



Medicare Prescription Drug & Medicare Reform Act

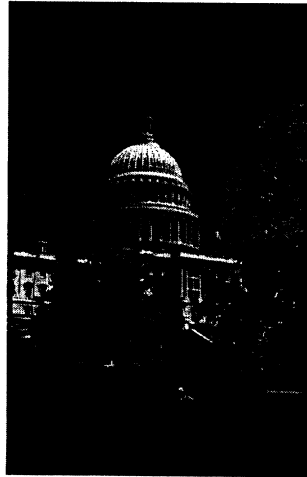
- Must control prescription drug costs if legislation is to:

- Provide adequate coverage
- Not bankrupt our economy

\$534 billion

- \$400 billion appropriated cost

■ ***\$1.9 trillion liability***



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Real Options to control prescription drug costs

- Negotiations and price controls
 - U.S. currently sets the prices for more prescription drugs than Canada
- Opening up U.S. prescription drug pricing to world competition and free trade



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Pharmaceutical Market Access Act

- **House Sponsored by Reps. Gil Gutknecht, Bernie Saunders, and Ron Emanuel**
- **Senate Sponsored by Byron Dorgan, Olympia Snowe, John McCain and Mark Dayton**
- **Allows individuals, wholesalers & pharmacists to import from FDA approved facilities in 25 countries**
- **Raises drug safety with Platinum standard against counterfeiting**

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Importation Legislation

– ***“Markets are more powerful than armies”***

- Ronald Reagan

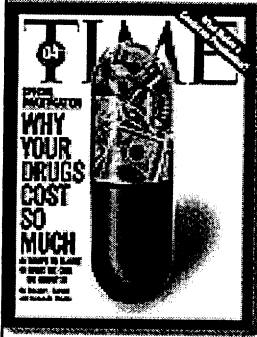
– **“Importation could save Medicare beneficiaries alone over \$630 billion during the next ten years.”**

– Congressman Gil Gutknecht

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The Tide is Turning... Time Magazine Cover Story



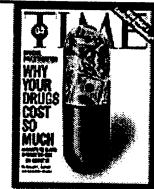
- Looked at the cost of Drugs in the U.S.A.
- Looked at FDA and PHARMA claims safety risks and legal risks from buying from Canada and other EU Countries

February 2, 2004

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Time Investigation reveals



- “The FDA's actions against Canadian imports have been part of a concerted campaign to simultaneously discredit its counterpart agency in Canada,
- Provoke fear among American consumers who buy their drugs there,
- Blunt an exploding political movement among local and state governments to begin wholesale drug buys in Canada and
- Ultimately preserve the inflated prices charged U.S. consumers and taxpayers.

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An Rx for drug costs

Prescription drug pricing

Drug	Dosage/number of tablets	MINNESOTA	CANADA
LIPITOR	High cholesterol 20 mg/60	\$273.87	\$180.75
SYNTHROID	Hypothyroidism 0.100 mg/100	\$56.50	\$11.60
PREMARIN	Hormone replacement 0.625 mg/1.00	\$102.00	\$29.75

Source: Star Tribune research, Minnesota Senior Federation
More price comparisons on A15.

The governor presented a groundbreaking plan to access cheaper prescription drugs in Canada.

By Warren Wolfe
Star Tribune Staff Writer

Within months, Minnesotans will be able to buy cheaper prescription drugs from Canada, in the United States' first state-sponsored mail-order program, Gov. Tim Pawlenty announced Thursday.

In the fractious national debate about high drug costs, Pawlenty's move cranks up pressure on the Bush administration, which opposes drug importation.

And it puts Minnesota squarely in

the forefront of a dozen states seeking to cut rising drug costs for their employees, residents and welfare programs.

"We're here because nobody's taken effective action," the governor said at a Capitol news conference. "Collectively, the system has been unresponsive to an obvious need that has now reached a crisis point." Federal officials, he added, have been "asleep at the switch."

DRUGS continue on A15:
— Minnesotans will be able to access the plan through a state Web site.

"A fire in the Heartland"

Friday
Star Tribune
Metro Edition



Minnesota Takes Leadership

Minnesotans could get access to the program through a state Web site — modeled after a similar program available for a year through the Minnesota Senior Federation — and a toll-free phone number.

Drug	Dosage/number of tablets	MINNESOTA	CANADA
NORVASC	High blood pressure 10 mg/100	\$187.50*	\$180.71
ZOLOFT	Depression 25 mg/100	\$251.77*	\$79.51
ZOCOR	High cholesterol 20 mg/100	\$355.47*	\$204.98
PAXIL	Depression/ panic disorder 20 mg/100	\$181.57*	\$158.77

* Prices available Thursday at

Source: Star Tribune research, Minnesota Senior Federation

Minneapolis, St. Louis Park

* Prices available at Canada through Minnesota Senior Federation. Pricing does not include mailing fees of \$2.00 to \$22.00 per order.

Minneapolis, St. Louis Park

not guarantee that imported drugs are not tainted, counterfeit or improperly stored or handled.

Sen. Norm Coleman, R-Minn., echoed that worry. "My big concern is don't raise expectations that can't be met. I can tell you the FDA still doubts whether this, in fact, can be done," he said Thursday.

But Pawlenty's commissioner of human services, Kevin Condon, said state officials believe this can work. "We think we can make it," he said.

While any Minn.

could use the program to buy drugs — a patient's physician would fax a prescription to Canada, and the drugs would be mailed to the patient — the state may offer incentives for state employees to do so, perhaps waiving co-payments.

In addition, officials will talk with pharmaceuticals, insurers and others to determine whether the state can buy or make available FDA-approved foreign-made drugs through drugstores. Under current law, U.S.-manufactured drugs

could use the program to buy drugs — a patient's physician would fax a prescription to Canada, and the drugs would be mailed to the patient — the state may offer incentives for state employees to do so, perhaps waiving co-payments.

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AT A GLANCE

Under the prescription drug plan presented Thursday by Gov. Pawlenty, his administration would:

- Create a Web site and toll-free phone line providing access to help Minnesotans buy prescription drugs from Canadian sources. The state would staff help centers to assist consumers.
- Offer a "checklist" — contracts, medical information, drug history — to encourage consumers to buy from Canada.
- Encourage seniors to report FDA-approved foreign-made drugs from Canada to the state's drug cost database.
- Create a prescription drug cost database to track drug prices.
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- Create a prescription drug cost database to track drug prices.

Thompson has his preference in the Clinton administration, Donna Hulsdale, had been willing to do.

"Some people argue we shouldn't be importing foreign price controls, but we import the regulations of other countries whenever we import their goods," Pawlenty said.

Praise from Hatch
The governor's plan was praised by Minnesota Attorney General Mike Hatch — a DFLer and frequent critic of Pawlenty, a Republican. Hatch said he was "impressed and pleased by this bold, innovative move."

In an opinion sought by the governor, Hatch advised two weeks ago that "the time for

"pushing the envelope" — and that would be just over this issue."

The U.S. House plan, sponsored by Rep. Gil Knecht, R-Minn., to allow importation of drugs from Canada and elsewhere. That proposal is part of current negotiations between the House and Senate over a law to add a benefit to the federal Medicare program.

Pawlenty predicted the plan would fuel the debate over a "groundwater" support and participation will rise to the level that Congress and the federal government will have change.

Friday
Star Tribune
Metro Edition

Lessons Learned:



- **Canadian Drug Supply is Safer than U.S. Drug Supply**
 - No example of any counterfeit or contaminated drug from any Canadian licensed pharmacy
- **Current FDA policies encourage counterfeiting & contaminated drugs**
- **It is the buyer beware:**
 - This country- whether down the street
 - Through the mail
 - Or over the Internet
 - You need to know who you are dealing with
- **Be willing to trust the oversight of drug supply by other countries as being as good or better than U.S. oversight**

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Lessons Learned:

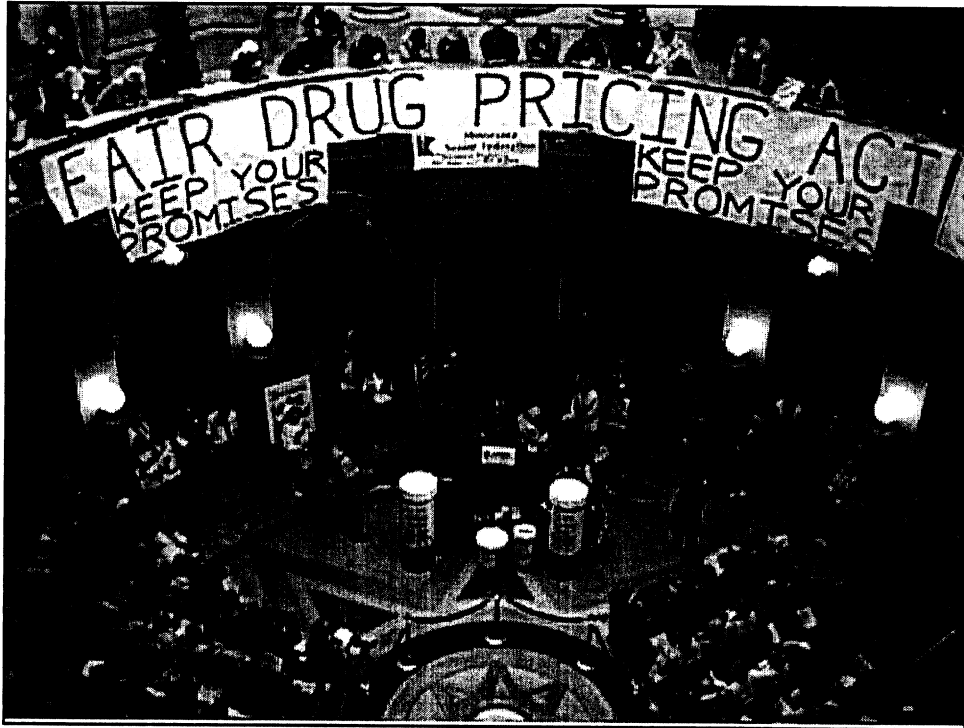


- **Your current policies are harming health and safety of Americans,**
 - Bringing about the demise of community pharmacies, and bankrupting the American Health Care system, for the sake of the greed of multi-national pharmaceutical companies
- **The FDA has destroyed the confidence of the American people in the FDA and of the political process**
 - We need an FDA that is concerned about the affordability of drugs in this country as least,
 - As much as you are concerned about the profitability of international pharmaceutical industry

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Programs and Activism....

On Behalf of

All Generations



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